

# Formal Action # 98-1330-I

IN THE CHANCERY COURT OF TENNESSEE, KNOX COUNTY  
SIXTH JUDICIAL DISTRICT AT KNOXVILLE

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STATE OF TENNESSEE,  
Plaintiff,

v.

MID-SOUTH PCM GROUP, P.C.,  
INTERNATIONAL COMPUTERIZED  
ORTHOKERATOLOGY SOCIETY, INC.,  
EYE AND VISION CLINIC, P.C., and  
J. MASON HURT, O.D.,

Respondents.

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## **ASSURANCE OF VOLUNTARY COMPLAINE**

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THIS ASSURANCE OF VOLUNTARY COMPLIANCE ("Assurance") is given by Mid-South PCM Group, P.C., International Computerized Orthokeratology Society, Inc., Eye and Vision Clinic, P.C., and J. Mason Hurt, O.D., ("Respondents"), to John Knox Walkup, Attorney General and Reporter for the State of Tennessee ("Attorney General").

### **WITNESSETH:**

Some of the facts and circumstances surrounding the execution of this Assurance are as follows:

A. The Division of Consumer Affairs of the Department of Commerce and Insurance (the "Division") and the Attorney General conducted an investigation of specific business practices of Respondents. These practices include making false or misleading claims in the marketing of optometric goods and services. Respondents' business practices are more fully described in the accompanying Petition. As a result of the investigation, the Division and the Attorney General determined that certain acts and practices of Respondents violated the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47-18-101, et seq. (the "Act").

B. This Assurance of Voluntary Compliance is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Petition and Assurance of Voluntary Compliance.

C. Therefore, pursuant to Tenn. Code Ann. § 47-18-107, Respondents desire to give this Assurance, and the Attorney General desires to accept it, in order to avoid the expense of litigation.

NOW, THEREFORE, acting pursuant to Tenn. Code Ann. § 47-18-107, Respondents give, and the Attorney General accepts, the following assurances:

### **1. DEFINITIONS**

As used in this Assurance, the following terms shall have the following meanings:

A. "Advertising" means any oral, written, graphic or pictorial statement or representation used to induce, directly or indirectly, any person to enter into any obligation or acquire any title or interest in any goods or services, regardless of the medium of communication employed, and includes product packages, labels and product inserts.

B. "Competent and reliable scientific evidence" means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, which has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

C. "Contact lens" means a thin lens designed to fit over the cornea to correct vision conditions.

D. "Corneal topography device" means an instrument designed to map the shape of the cornea.

E. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is recognized in the official United States Pharmacopoeia National Formulary or any supplement to it, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or intended to affect the structure or any function of the body of man or other

animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes.

F. "FDA" means the U.S. Food and Drug Administration.

G. "Orthokeratology" means the procedure of using contact lenses to reshape the cornea in hopes of eliminating or obviating the need for corrective eyewear.

H. "Precise Corneal Molding" or "PCM" is J. Mason Hurt's trade name for orthokeratology.

I. "Promotional material" means any materials such as sales brochures, leaflets, or other written, printed, or graphic matter, which accompanies a product.

J. "Retainer molds" means a contact lens worn to reshape the cornea or to maintain the effects of orthokeratology.

K. "Refractive Vision Deficiency" means any vision deficiency treatable by corrective lenses, including but not limited to nearsightedness (Myopia), farsightedness (Hyperopia), astigmatism (Distorted vision), and presbyopia (aging eyes).

## **2. BUSINESS PRACTICES**

Respondents Mid-South PCM Group, P.C., International Computerized Orthokeratology Society, Inc., Eye and Vision Clinic, P.C., and J. Mason Hurt, O.D., and their respective agents, representatives, successors and assigns are permanently enjoined from:

A. Introducing or delivering for introduction in Tennessee any contact lens promoted for PCM or any other type or brand of orthokeratology prior to submission of a pre-market notification as required by Section 510(k) of the Federal Food and Drug and Cosmetic Act, unless and until pre-market approval or an order of substantial equivalence for that device has been granted by the FDA;

B. Misbranding any contact lens or corneal topography device by making (a) any performance claim not previously approved by the FDA as an intended use for the device, (b) any claim that overstates the quality or value of a contact lens or corneal topography device, in labeling, promotional literature, or advertising, or (c) any claim that is not consistent with labeling claims permitted for the device by the FDA; Subject to the restrictions in Paragraphs 2(A) and 2(B), above, Respondents shall not make any of the following representations unless, at the time the representation is made, the representation is true and Respondents possess and rely upon competent and reliable scientific evidence substantiating the representation:

C. PCM or any other type or brand of orthokeratology provides a cure for any refractive vision

deficiency thereby permanently eliminating the need for all corrective eyewear, including eyeglasses and contact lenses;

D. All people can achieve normal vision without eyeglasses or contact lenses on a permanent basis if they wear PCM or any other type or brand of orthokeratology devices occasionally or at night;

E. PCM or any other type or brand of orthokeratology has been approved by the Federal Aviation Administration and all branches of the United States military for use in correcting refractive vision deficiencies;

F. Studies at the University of Houston College of Optometry (1976-77), University of California at San Diego Medical School (1980), University of California at Berkeley College of Optometry (1982-83), and Pacific University College of Optometry (1984), prove that PCM or any other type or brand of orthokeratology is safe and effective in correcting nearsightedness, farsightedness, and astigmatism;

G. Testimonials from consumers appearing in the advertisements for Respondents' PCM services claiming that Respondents' PCM patients typically achieve 20/20 vision and no longer need corrective eyewear reflect the typical or ordinary experience of members of the public who receive those services;

H. Respondents have scientifically substantiated the number of people who can achieve normal vision without eyeglasses or contact lenses on a permanent basis if they wear PCM or any other type or brand of orthokeratology devices occasionally or at night;

I. Respondents have scientifically substantiated the number of people who will experience stabilized vision after only a few weeks or months of PCM or any other type or brand of orthokeratology treatments;

J. Respondents have scientifically substantiated the ability of PCM or any other type or brand of orthokeratology to prevent or reverse deteriorating nearsightedness in children;

K. Respondents have scientifically substantiated the comparative safety of PCM or any other type or brand of orthokeratology versus contact lens wear;

L. Respondents have scientifically substantiated the comparative effectiveness of PCM or any other type or brand of orthokeratology versus refractive surgical methods in eliminating nearsightedness, farsightedness, and all forms of astigmatism;

M. Respondents have scientifically substantiated the number of people whom PCM or any other type or brand of orthokeratology has helped achieve normal vision.

### **3. RESTITUTION**

3.1 Respondents shall provide a refund to any consumer who files a complaint or refund request with Respondents, the Attorney General or the Division of Consumer Affairs within 90 days of the date this Assurance of Voluntary Compliance is entered. Refunds shall be made by check backed by good and sufficient funds and shall be mailed by first class United States mail within 20 days of Respondents' receipt of the complaint or refund request. Within 30 days of the end of the refund period, Respondents shall provide the Attorney General with a written report documenting their compliance with the terms of this provision. This report shall list in alphabetical order the name and address of each consumer who filed a complaint or refund request and the amount paid to each consumer.

**4. JURISDICTION**

4.1 Jurisdiction of this Court over the subject matter herein and over the persons of the Respondents for the purposes of entering into and enforcing this Assurance and Agreed Order is admitted. Jurisdiction is retained by this Court for the purpose of enabling the State to apply such further orders and directions as may be necessary or appropriate for the construction, modification or execution of this Assurance and Agreed Order, including enforcement of compliance therewith and assessment of penalties for violation(s) thereof.

**5. PAYMENT OF ATTORNEYS' FEES AND COSTS TO THE STATE**

5.1 Respondents shall pay the sum of Nine Thousand and 00/100 Dollars (\$9,000.00) to the State of Tennessee for attorneys' fees and costs of investigation, prosecution and monitoring for compliance of this matter, which may be used for consumer protection purposes at the sole discretion of the Attorney General. This payment shall be made by providing the Attorney General or his designated representative a cashier's or certified check made payable to the State of Tennessee as set forth in paragraph 7.

**6. CIVIL PENALTIES**

6.1 Respondents shall pay the sum of One Thousand and 00/100 Dollars (\$1,000.00) to the State of Tennessee for civil penalties in this matter. This payment shall be made by providing the Attorney General or his designated representative a cashier's or certified check made payable to the State of Tennessee as set forth in paragraph 7.

**7. PAYMENT OF ATTORNEYS' FEES AND COSTS AND CIVIL PENALTIES**

7.1 Payments due under this Assurance of Voluntary Compliance shall be made as follows:

A.	On January 1, 1999	\$2,500.00
B.	On March 1, 1999	\$2,500.00
C.	On May 1, 1999	\$2,500.00
D.	On July 1, 1999	\$2,500.00

7.2 Respondents' failure to make any payment required by this Assurance shall be deemed an act of default. Upon such default, all remaining amounts are immediately due and owing, and shall be subject to simple interest of ten percent per annum. Additionally, Respondents agree to pay attorneys' fees and costs, including court costs associated with any collection efforts required to collect the remaining amounts owed the State.

7.3 No execution or garnishment on the monetary portion of this Assurance shall issue so long as Respondents make payments in accordance with the terms of this Assurance. In the event Respondents fail to make any such payment when due, the entire balance may be collected by execution, garnishment or other legal process, together with interest pursuant to Tenn. Code Ann. § 47-14-121 from the date of entry of this Assurance. Respondent further agrees that this Assurance and the accompanying Agreed Order are a judgment for which execution may issue pursuant to Tennessee law.

7.4 Payments made under this Assurance shall be allocated first to attorneys' fees and costs and then to civil penalties.

## **8. MONITORING AND COMPLIANCE**

8.1 Upon request, Respondents agree to provide books, records and documents to the State at any time, and further, to informally or formally under oath, provide testimony and other information to the State relating to compliance with this Assurance. Respondents shall make any requested information reasonably available within one (1) week of the request, at the Office of the Attorney General or at any other location within the State of Tennessee that is agreeable to Respondents and the Attorney General. This section shall in no way limit the State's right to obtain documents, information, or testimony pursuant to any federal or state law, regulation, or rule.

## **9. PRIVATE RIGHT OF ACTION**

9.1 Pursuant to Tenn. Code Ann. § 47-18-109, nothing in this Assurance shall be construed to affect any private right of action that a consumer may hold against Respondent.

## **10. PENALTY FOR FAILURE TO COMPLY**

10.1 Respondents understand that upon execution and filing of this Assurance, any subsequent failure to comply with the terms hereof is prima facie evidence of a violation of the Tennessee Consumer Protection Act.

10.2 Respondents understand that any knowing violation of the terms of this Assurance is punishable by civil penalties of not more than One Thousand Dollars (\$1,000.00) for each violation, in addition to any other appropriate penalties and sanctions, including but not limited to contempt sanctions and the imposition of attorneys' fees and civil penalties.

## **11. VENUE**

11.1 Pursuant to Tenn. Code Ann. § 47-18-107, venue as to all matters between the parties relating hereto or arising out of this Assurance is solely in the Chancery Court of Davidson County, Tennessee.

## **12. REPRESENTATIONS AND WARRANTIES**

12.1 Respondents represent and warrant that the execution and delivery of this Assurance is their free and voluntary act, that this Assurance is the result of good faith negotiations, and that Respondents believe that the Assurance and terms hereof are fair and reasonable. The parties warrant that they will implement the terms of this Assurance in good faith.

12.2 Respondents represent that the signatories to this Assurance have authority to act for and bind the Respondents.

12.3 Respondents will not participate, directly or indirectly, in any activity to form a separate entity or corporation for the purpose of engaging in acts set forth and prohibited in this Assurance or for any other purpose which would otherwise circumvent any part of this Assurance.

12.4 Neither Respondents nor anyone acting on their behalf shall state or imply or cause to be stated or implied that the Attorney General, the Division, or any other governmental unit of the State of Tennessee approved, sanctioned, or authorized any practice, act, or conduct of the Respondents.

12.5 Acceptance of this Assurance by the State shall not be deemed approval by the State of any of Respondents' advertising or other business practices.

12.6 Within thirty (30) days of the entry of this Assurance, Respondents shall submit a copy of this Assurance to each of its officers, directors, employees and any third parties who act directly or indirectly on behalf of the Respondents as an agent, independent contractor or who are, involved in conducting business in the State of Tennessee. Within forty-five (45) days of entry of this Assurance, Respondents shall provide the State with an affidavit verifying and certifying that all required persons have been supplied with a copy of this Assurance.

12.7 Respondents warrant and represent that it they are the proper parties to this Assurance and Order. Respondents further acknowledge that the State expressly relies upon this representation and warranty, and that if it is false, misleading or inaccurate, the State may move to vacate or set aside this Assurance and Agreed Order, and may request that Respondents be held in contempt.

12.8 Respondents represent that the names set out in the caption of this Assurance are the true legal names of the individual and corporate entities entering into this Assurance of Voluntary Compliance and Agreed Order. Respondents understand that the State expressly relies upon this representation and if this

representation is false or misleading, the State may move to vacate or set aside this Assurance and Agreed Order, and may request that Respondents be held in contempt.

12.9 This Assurance and Agreed Order may only be enforced by the parties hereto.

12.10 The titles and headers to each section of this Assurance are for convenience purposes only and are not intended by the parties to lend meaning to the actual provisions of the Assurance.

12.11 This document shall not be construed against the "drafter" because both parties participated in the drafting of this document.

12.12 This Assurance and Agreed Order constitute the complete agreement of the parties with regard to the resolution of the matters set forth in the State's Petition. This Assurance is limited to resolving only matters set forth in the State's Petition.

12.13 Nothing in this Assurance shall be construed to limit the authority of the Attorney General to protect the interests of the State or the people of the State of Tennessee. In addition, this Assurance shall not bar the State or other governmental entity from enforcing laws, regulations or rules against Respondents, other than as set forth in this Assurance.

12.14 This Assurance shall be binding and effective against Respondents upon Respondents' signing the Assurance.

### **13. COMPLIANCE WITH OTHER LAWS**

13.1 Nothing in this Assurance and Order shall be construed as relieving Respondents of the obligation to comply with any state or federal law, regulation or rule.

### **14. FILING OF ASSURANCE**

14.1 Upon the execution of this Assurance, the Attorney General shall prepare and file in the Chancery Court for Davidson County a Petition, Agreed Order and this Assurance for the Court's approval. Respondents hereby waive any and all rights they may have to be heard in connection with judicial proceedings upon the Petition. Respondents agree to pay all costs of filing such Petition, Assurance and Agreed Order. Simultaneously with the execution of this Assurance, Respondents shall execute an Agreed Order. This Assurance is made a part of and is incorporated into the Agreed Order.

### **15. APPLICABILITY OF ASSURANCE TO RESPONDENTS AND ITS SUCCESSORS**

15.1 Respondents agree that the duties, responsibilities, burdens and obligations undertaken in connection with this Assurance shall apply to Respondents, Respondents' officers, directors, agents or other persons and entities they control, manage or operate, their successors and assigns, and to other



persons or entities acting directly or indirectly on their behalf.

## **16. COSTS**

16.1 All costs associated with the filing and distribution of this Assurance and any other incidental costs or expenses incurred thereby shall be borne by Respondents. No costs shall be taxed against the State as provided by Tenn. Code Ann. § 47-18-116. Further, no discretionary costs shall be taxed to the Respondents.

## **17. NOTIFICATION TO STATE**

17.1 For five (5) years following execution of this Assurance, Respondents shall notify the Attorney General, c/o Consumer Protection Division, 425 Fifth Avenue North, 2nd Floor, Nashville, Tennessee 37243-0491, in writing, at least thirty (30) days prior to the effective date of any proposed changes in the corporate structure, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation or firm, the creation or dissolution or subsidiaries, or any other changes in Respondents' status that may effect compliance with obligations arising out of this Assurance.